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| EXAMINER | |
|---|---|
| GREENE, IVAN A | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/564,635 | FUNDA ET AL. | |
| | Examiner | Art Unit | |
| | IVAN GREENE | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the claims*

Claims 1-17 are currently pending.

### *Information Disclosure Statement*

The information disclosure statements (IDS) submitted on 10/11/2006 and 07/13/2007 were filed before the first office action. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The effective US filing date of the instant application has been determined to be 07/06/2004 the filing date of the PCT document PCT/EP04/07367.

### *Objections*

The specification contains the incomprehensible phrase, "The spraying can effected be using conventional technology of spray-drying," (pg. 3, lines 22 & 23). Examiner suggests the phrases should read, "The spray-drying can be accomplished by using conventional technology of spray-drying,..." Appropriate correction is required.

The specification contains the misspelled words –especiall--- (pg. 2, line 30; pg. 3, line 6) and –werde-- (pg. 5, line 5). Appropriate correction is required.

***Claim Rejections - 35 U.S.C. 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-13 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 1 is rejected because of the limitations --reducing sugar derivative--; claim 9 is rejected because of the limitations --carbohydrate derivative-- and --cellulose derivatives--; claim 17 is rejected because of the limitation --reducing sugar derivative--. The 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield, Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." For example, rayon could theoretically be derived from cellulose or carbon powder could theoretically be derived from sugar or carbohydrate. Therefore, the definition of derivative in the Merriam-Webster Collegiate Dictionary does not shed light on what Applicants' intended for the meaning of --reducing sugar derivative-- (claims 1 & 17), --carbohydrate derivative-- and --cellulose derivatives-- (claim 9).

2. Regarding claims 9 and 13, the phrase "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

3. Instant claim 13 recites –if appropriate--. It is a matter of subjective interpretation what exactly the term "if appropriate" means. The specification gives no guidance as to what would

render the step appropriate. Claim 13 is rejected because it cannot be determined what exactly is meant by –if appropriate--.

4. Claim 9 also recites the phrase --especially such in the range of-- which renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. Is the limitation "dextrins and maltodextrins" or "dextrins and maltodextrins in the range of 5-65 dextrose equivalents;" is the limitation "glucose syrup" or "glucose syrup in the range of 20-95 dextrose equivalents?" Claim 9 is rendered indefinite by the phrase – especially such in the range of--.

The remaining claims are rejected as depending from a rejected claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**1. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al. (US Patent No. 5,356,636) in view of Bewert et al. (European patent EP 0982038) and Kodera et al. (US Patent No. 6,455,273) as evidenced by Aria et al. (US Patent No. 4,921,705), Gerrard (Trends in Food Science and Technology, 13, 2002, pgs. 391-399), and Hamaguchi (US Patent No. 5,127,953).**

**Applicants claim**

Applicants claim stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a native or partially hydrolyzed milk protein composition, wherein the protein is thermally cross-linked with a reducing sugar. Applicants further claim the stable powderous milk protein composition comprises a plant protein with an average molecular weight below 2500 Daltons. Applicants further claim the stable powderous milk protein composition wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid, or ester thereof. Applicants further claim food, beverages, animal feeds, cosmetics or drugs comprising the aforementioned milk protein formulations. Applicants further claim a process for preparing milk protein formulations comprising: preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking the protein by heat treatment.

**Determination of the scope and content of the prior art (MPEP 2141.01)**

Schneider et al. teaches, a process for preparing stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids comprising preparing an aqueous emulsion of the fat-soluble active ingredient, a film-forming colloid (gelatin) and a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking of the proteins by heat treatment (abstract).

Schneider et al. further teaches, "The fat-soluble vitamins include vitamins A, E, D and K as well as mixtures thereof. For the purpose of the present invention they can be employed in the form of vitamin solutions in oils...Particularly interesting products contain vitamin A and its derivatives, especially vitamin A acetate, vitamin A palmitate..." (col. 3, lines 59-66). Schneider et al. further teaches, the sugars can be any reducing sugars or syrup containing reducing sugars including fructose, glucose, lactose, maltose, xylose, arabinose, ribose and invert sugar (col. 4, lines 11-17). Schneider et al. further teaches, "In addition to the obligatory ingredients, it is advantageous to add to the dispersion other compounds customary in the preparation of active substance dry powders" (col. 4, lines 59-63). Schneider et al. goes on to teach the additives starch (col. 5, line 9) and hydrophobic silica (col. 4, line 42).

Examiner notes Schneider et al. teaches that casein does not form thermo-reversible gels (col. 3, lines 3-8), but may be obtained as fine water-dispersible particles. This teaching is not considered teaching away from the use of casein because Schneider et al. does not suggest that casein could not be used in the process they describe. Examiner further notes the prior art which teaches modified protein food additives often suggest the use of gelatin or casein; see Bewert et al. ([0017]), Aria et al. (col. 2, lines 52-58); Hamaguchi (col. 4, lines 39-45).

**Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

The difference between the rejected claims and the teachings of Schneider et al. is that Schneider et al. does not explicitly teach milk proteins or addition of a plant protein or plant protein hydrolysate with an average molecular weight of less than 2500 Daltons. The deficiency of using the milk protein casein is cured by Bewert et al. The deficiency of the addition of a plant protein or plant protein hydrolysate is cured by the teachings of Kodera et al.

Bewert et al. teaches dry powder formulations comprising fat-soluble active ingredients in a cross-linked protein matrix ([0001]). Bewert et al. further teaches the preferred proteins are gelatin, casein, soy protein, corn protein and collagen ([0017]). Bewert et al. further teaches the release agents silicic acid and corn starch ([0022]). Bewert et al. further teaches the preferred cross-linking agent is the enzyme transglutaminase ([0026]). Bewert et al. further teaches preferable fat-soluble active ingredients are vitamin of the group A, D, E and K, or carotenoids ([0027]).

Examiner notes, Bewert et al. suggests the disadvantages for cross-linking with a reducing sugar using heat treatment are degradation of the active ingredient and browning of the final product; however, from the prior it is clear that there are both advantages and disadvantages for cross-linking base on heat treatment vs. chemical or enzymatic treatment. For example, cross-linking using aldehydes or ketones, may cause residual cross-linking with time. Gerrard suggests the use of enzymes is favored by consumers as more "natural" and they require milder conditions to act; however, the disadvantage of enzymes is their higher cost vs. thermal and chemical cross-linking approaches. Chemical modification of food products, while more cost effective, is not

desirable because of harsh reaction conditions, non-specific chemical reaction reagents and difficulty of removing chemical reaction reagents from the final product.

Kodera et al. teaches a method for producing a protein hydrolysate with low bitterness (abstract) for use in foodstuffs, infant formulas, medicinal diets, seasonings, flavor-modifying materials, food-property modifying materials, food additives and feeds (col. 2, lines 10-20). Kodera et al. further teaches, the protein substrate for their invention is preferably a vegetable protein, such as, soy bean or gluten or an animal protein such as casein or gelatin (col. 4, lines 8-18). Kondera et al. further teaches the range of the molecular weights of the protein hydrolysate is preferably 200 to 2000 daltons (col. 4 , lines 28-32). Kodera et al. further teaches the product of their invention can be used by incorporation into a variety of food products (col. 4, lines 56-63).

**Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the stable dry powder of Schneider et al. with the stable dry powder based on casein of Bewert et al. because they both teach stable dry powdered food additives containing a fat-soluble vitamin ingredients.

The processing of foods, which is common place in modern society, provides for an increased shelf life, consistent and appealing texture, and enhanced flavor. Cross-linking of proteins provides a means for controlling the functional properties of foods, such as the texture. A cross-linked protein can also provide a matrix for additional beneficial ingredients such as fat-soluble vitamins. A dry powdered product would be very desirable for functional proteins for use

as food additives because the storage conditions would be more favorable and the shipping costs would be reduced. It would have been prima facie obvious that vitamin enrichment would provide for a more nutritious and therefore desirable product. Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a stable dry vitamin powder. See MPEP 2144.06.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the stable dry powder of Schneider et al. with the plant protein hydrolysate of Kondera et al. because it would produce a more nutritive food additive. Furthermore, a plant protein with a low average molecular weight would provide for a more easily ingestible food product as taught by Kodera et al. (col. 2, line 13).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success , for example the prior art teaches cross-linking of different proteins using various methods, as discussed above.. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Nonstatutory Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 12-14, 16 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-9, 11 and 13 of copending Application No. 10/551,197 (hereafter referred to as '197) in view of Bewert et al. and Doxastakis (Novel Macromolecules in Food Systems, pgs 7-38).

Instant claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein compositions, wherein the protein is thermally cross-linked with a reducing-sugar. Copending '197 claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of native lupin protein composition wherein the protein is cross-linked; copending '197 claim 11 recites, a process wherein a reducing sugar is added and the composition is submitted cross-linking by heating. The difference between the claim of copending '197 and the instant claimed invention is the primary cross-linking protein.

Instant claims 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; instant claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Copending '197 claim 6 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or carotenoids, or a polyunsaturated fatty acid; copending '197 claim 7 recites form formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Instant claims 12 and 13 are coextensive in scope with copending '197 claims 6 and 7.

Instant claim 14 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Copending '197 claim 8 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Instant claim 14 is coextensive in scope with copending '197 claim 8.

Instant claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment. Copending '197 claim 13 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the native lupin protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein by heat treatment or by treatment with a cross-linking enzyme. The difference between instant claim 17 and copending '197 claim 13 is the primary cross-linking protein and the alternative possibility of enzymatic cross-linking copending '197 claim 13.

The difference between Copending '197 and the instant claimed invention is that copending '197 does not explicitly teach the use of native milk protein for the primary cross-linking protein. The deficiency of using a native milk protein is cured by the teachings of Bewert et al. teaches dry powder formulations comprising fat-soluble active ingredients in a cross-linked protein matrix wherein the preferred protein is casein, as discussed above. Bewert further teaches, preferred cross-linkable proteins are gelatin, casein, soy protein, corn protein and collagen ([0017]). Doxastakis teaches lupins belong to the legume group of plants and are able to grow in marginal soils, enabling the plant to grow in many environments (pg. 7, lines 1-6). Doxastakis further teaches, "Interest in a wider utilization of lupin seeds is mainly due to its similarity to soybeans as a high source of protein and to the fact that it can be grown in more temperate climates and is tolerant of poor soils (pg. 7, lines 18-20). .

It would have been prima facie obvious to combine copending '197 with the teachings of Bewert et al. and produce the instant claimed invention because both copending '197 and Bewert et al. teach dry powdered food additives with cross-linked protein and a fat-soluble active ingredient in the protein matrix. It is prima facie obvious to combine similar compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a stable dry vitamin powder. See MPEP 2144.06.

It would have been prima facie obvious to combine copending '197 with the teachings of Doxastakis and Bewert et al. because Bewert et al. teaches that casein and soy can be used interchangeably with their invention and Doxastakis teaches that lupins are a viable alternative to

soybeans. Examiner notes the comprising language of copending '197 invites additional ingredients.

This is a provisional obviousness-type double patenting rejection.

***Conclusion***

Claims 1-17 are pending. Claims 1, 9, 13 and 17 are rejected under 35 USC § 112. Claims 1-17 are rejected under 35 USC § 103(a). Claims 1, 12-14, 16 and 17 are rejected on the grounds of nonstatutory double patenting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached Monday thru Thursday 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE
Examiner, Art Unit 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616